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APPLICANT: Kulkarni et al. EXAMINER: Cook, Rebecca
SERIAL NO.: 10/602,215 ART UNIT: 1614
FILED: 06/24/2003 PAPER NO.:
FOR: LIQUID PHARMACEUTICAL COMPOSITIONS

DECLARATION UNDER 37 CFR § 1.132

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Majid Mahjour, a citizen of the United States, residing at 2129 Autumn Hill Drive, Ann Arbor, Michigan 48103, hereby declare:

1. I received a Pharm. D. degree in Pharmacy from the University of Tehran, Iran in 1975. I received an M.S. degree in Pharmaceutical Chemistry from the Philadelphia College of Pharmacy in 1977. I received a Ph.D. in Pharmaceutics from the University of Michigan in 1980. I carried out post-doctoral studies at the University of Michigan and at the University of Utah between 1981 and 1983. I have authored or co-authored over

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. 1.8(a))

I hereby certify that, on the date shown below, this correspondence is being:

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- ☐ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

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- ☒ transmitted by facsimile to the Patent and Trademark Office, telephone number (703) 872-9306.

Date: May 27, 2005

Signature

Matthew J. Russo
(type or print name of person certifying)

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40 scientific articles/abstracts concerning pharmaceutical technology, and I am an inventor or co-inventor on eight United States Patents.

2. I joined the Parke-Davis Pharmaceutical Research Division of Warner Lambert Company in 1983 as a Scientist. Since that time, I have been promoted to Senior Scientist, Research Associate, Senior Research Associate, and Associate Director. I am currently a Research Fellow/Research Advisor. I have carried out research in the area of pharmaceutical formulations and delivery science.

3. I have studied the above-captioned patent application which describes liquid pharmaceutical compositions containing a GABA analog, such as gabapentin or pregabalin, and one or more polyhydric alcohols that comprise at least 25% weight/volume of the composition (claim 14) or about 25% to about 75% weight/volume of the composition (claims 1, 6, 9, and 10). According to the patent application, the pH of the each composition ranges from about 5.5 to about 7.0. The liquid pharmaceutical compositions may also include flavors and preservatives and may be used to treat cerebral diseases, such as epilepsy, faintness attacks, hypokinesia; cranial traumas, neurodegenerative disorders, depression, mania, bipolar disorders, anxiety, panic, inflammation, renal colic, insomnia, gastrointestinal damage, incontinence, migraine, or pain, including neuropathic pain, muscular pain, or skeletal pain.

4. In Table A, below, I provide long-term stability data for a pharmaceutical syrup composition currently marketed by Pfizer Inc. The syrup contains gabapentin, two polyhydric alcohols—glycerol and xylitol—artificial flavor, and purified water. Together, glycerol and xylitol makes up between 25% and 75% w/v of the total composition, and the pH of the composition is in the range of 5.5 to 7.0. The gabapentin syrup is similar to the liquid pharmaceutical compositions shown in Table 1 of the present application.

5. The data in Table A demonstrate that the gabapentin syrup is stable. For gabapentin syrup samples stored at 5°C for up to 24 months, the lactam concentration

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was 0.1 % or less, based on weight of gabapentin. For gabapentin syrup samples stored at 25°C for 6 months, the lactam concentration was 0.4 % or less, based on weight of gabapentin.

6. I further declare that all statements made herein of my knowledge are true and that all statements made on information are believed to be true; and further that the statements were made with my knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code and that said willful false statements may jeopardize the validity of the application or any patent issued thereon.

5-27-2005

Date

Majid Mahjour

Majid Mahjour, Ph.D.

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Table A. Long-Term Stability Data for Gabapentin Syrup (gabapentin % label claim; lactam % of gabapentin)

Analyte	Temp. °C	Config.	Drug Lot	Initial %	Initial pH	3 m %	6 m %	6 m pH	9m %	9 m pH	12 m %	18 m %	24 m %	24 m pH
Gabapentin	5	upright	775782	100	6.6	98.8	98.6	6.5	99.7	6.4	99.4	99.6	99.1	6.4
Lactam	5	upright	775782	0.01		0.02	0.02		0.06		0.05	0.1	0.1	
Gabapentin	25	upright	775782			99.3	98.7	6.3						
Lactam	25	upright	775782			0.3	0.3							
Gabapentin	5	on side	775782	100	6.6	98.7	98.5	6.5	99.8	6.3	99.5	100.1	99.2	6.3
Lactam	5	on side	775782	0.01		0.02	0.03		0.06		0.05	0.1	0.1	
Gabapentin	25	on side	775782			99.7	98.1	6.3						
Lactam	25	on side	775782			0.3	0.3							
Gabapentin	5	upright	775782-271	99.7	6.6	99.6	99.6	6.4	100.4	6.4	100.4	100.2	99.7	6.4
Lactam	5	upright	775782-271	0.01		0.02	0.03		0.07		0.05	0.1	0.1	
Gabapentin	25	upright	775782-271			100.2	98.7	6.3						
Lactam	25	upright	775782-271			0.3	0.3							
Gabapentin	5	on side	775782-271	99.7	6.6	99	99.5	6.5	100.9	6.4	100.4	100	100.1	6.4
Lactam	5	on side	775782-271	0.01		0.02	0.02		0.08		0.05	0.1	0.1	
Gabapentin	25	on side	775782-271			99.5	98.5	6.3						
Lactam	25	on side	775782-271			0.3	0.3							
Gabapentin	5	upright	775271	99.7	6.6	99.4	99.6	6.4	100.4	6.3	100.9	99.8	99.6	6.3
Lactam	5	upright	775271	0.02		0.02	0.02		0.06		0.04	0.1	0.1	
Gabapentin	25	upright	775271			100.3	98.8	6.2						
Lactam	25	upright	775271			0.3	0.3							
Gabapentin	5	on side	775271	99.7	6.6	99.4	99.2	6.4	100.3	6.4	101.2	99.9	99.7	6.3
Lactam	5	on side	775271	0.02		0.02	0.02		0.07		0.05	0.1	0.1	
Gabapentin	25	on side	775271			100	99.1	6.2						
Lactam	25	on side	775271			0.3	0.3							

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Analyte	Temp. °C	Config.	Drug Lot	Initial %	Initial pH	3 m %	6 m %	6 m pH	9m %	9 m pH	12 m %	18 m %	24 m %	24 m pH
Gabapentin	5	upright	781276	101.1	6.6	101.2	102.4	6.5	100.4	6.5				
Lactam	5	upright	781276	0.01		0	0.02		0.04					
Gabapentin	25	upright	781276			100.7	100.1	6.3						
Lactam	25	upright	781276			0.2	0.4							
Gabapentin	5	on side	781276	101.1	6.6	100.9	101	6.5	101.1	6.5				
Lactam	5	on side	781276	0.01		0	0.02		0.04					
Gabapentin	25	on side	781276			101	99.7	6.3						
Lactam	25	on side	781276			0.2	0.4							
Gabapentin	5	upright	781276	100.3	6.7	100.5	100.2	6.6	100.4	6.5				
Lactam	5	upright	781276	0.01		0	0.02		0.03					
Gabapentin	25	upright	781276			100.2	98.3	6.3						
Lactam	25	upright	781276			0.2	0.4							
Gabapentin	5	on side	781276	100.3	6.7	100.7	100.3	6.6	100.4	6.5				
Lactam	5	on side	781276	0.01		0	0.02		0.04					
Gabapentin	25	on side	781276			99.9	98.3	6.3						
Lactam	25	on side	781276			0.2	0.4							
Gabapentin	5	upright	781276	101.6	6.6	100.6	100.5	6.5	99.8	6.5				
Lactam	5	upright	781276	0.01		0	0.01		0.03					
Gabapentin	25	upright	781276			100.9	99.2	6.4						
Lactam	25	upright	781276			0.2	0.4							
Gabapentin	5	on side	781276	101.6	6.6	100.9	100.1	6.4	100.2	6.5				
Lactam	5	on side	781276	0.01		0	0.02		0.03					
Gabapentin	25	on side	781276			100.3	98.8	6.4						
Lactam	25	on side	781276			0.2	0.4							

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